

Duke University Medical Center

DURHAM, NORTH CAROLINA
27710

DEPARTMENT OF MEDICINE
DIVISION OF RHEUMATOLOGY
AND IMMUNOLOGY
APPOINTMENTS: (919) 668-7630

PO BOX 2978 DUMC
TELEPHONE: (919) 684-8844
FAX: (919) 681-8298
EMAIL: CALDW009@MC.DUKE.EDU

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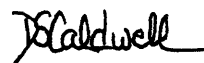
Ms. Kimberly Topper
Food and Drug Administration, CDER
Advisors and Consultant Staff, HFD-21
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket Number 01N-0256

Dear Ms. Topper:

As a rheumatologist at an academic center, I am frequently asked to evaluate patients with chronic pain. Among those in the chronic pain category are elderly individuals with advanced osteoarthritis. Many of those patients are non-operative candidates and most by the time I am asked to see them have exhausted conventional therapies including nonsteroidal anti-inflammatory drugs. Either the drug was not particularly helpful or could not be tolerated or the patient had some other prevailing medical problem that precluded use of such an agent. For these patients opiate analgesics are vital. One never forgets the risk of such therapy and certainly weighs such with each prescription, however, the benefit for that particular group of patients is substantial. It is hoped that availability of opiates for this particular population as well as others where options are very limited will not be substantially restricted or the access to such therapy hampered.

Thank you,



David S. Caldwell, MD, FACP, FACR
Associate Professor

DSC/dwo